Introductory Comment:

Licensee denotes users of radioactive material and registrant denotes users of electronically-produced ionizing radiation. References to "registrant" were removed from rules dealing only with radioactive material. References to "licensee" were removed from rules dealing only with electronically-produced ionizing radiation.

PART D STANDARDS FOR PROTECTION AGAINST RADIATION

General Provisions

Rule D.1001 - Purpose.

a. This part establishes standards for protection against ionizing radiation resulting from activities conducted under licenses or registrations issued by the department. These rules are issued under Part 135 of 1978 PA 368, as amended, MCL 333.13501 to 333.13538.

b. The requirements of this part are designed to control the receipt, possession, use, transfer, and disposal of sources of radiation by a licensee or registrant so that the total dose to an individual, including doses resulting from all sources of radiation other than background radiation, does not exceed the standards for protection against radiation prescribed in this part. Nothing in this part shall be construed as limiting actions that may be necessary to protect health and safety.

Rule D.1002 - Scope.

This part applies to a person licensed or registered by the department to receive, possess, use, transfer, or dispose of sources of radiation. The limits in this part do not apply to doses due to background radiation, to exposure of patients to radiation for medical diagnosis or therapy, to exposure from individuals administered radioactive material and released under Rule G.40, or to exposure from voluntary participation in medical research programs.

Rule D.1003 - Definitions.

Definitions will be added later.

Rule D.1004 - Implementation.

a. If the requirements of this part are more restrictive than a license or registration condition established before [effective date of these rules], the licensee or registrant shall comply with this part unless exempted by subrule c. of this rule.

b. An existing license or registration condition that is more restrictive than this part remains in force until the license or registration is amended or renewed.

c. If a license or registration condition exempts a licensee or registrant from a provision of this part in effect before [effective date of these rules], it also exempts the licensee or registrant from the corresponding provision of this part.

d. If a license condition cites a provision of 10 CFR Part 20 in effect before [effective date of these rules] that does not correspond to a provision of this part, the license condition remains in force until a license amendment or renewal modifies or removes the condition.

Radiation Protection Programs

Rule D.1101 - Radiation Protection Programs.

a. A licensee or registrant shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed or registered activities that ensures compliance with the provisions of this part. Rule D.2102 provides recordkeeping requirements relating to these programs.

b. To the extent practical, a licensee or registrant shall use procedures and engineering controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as reasonably achievable (ALARA).

c. The licensee or registrant shall, at least annually, review the radiation protection program content and implementation.

d. To implement the ALARA requirements of subrule b. of this rule and notwithstanding the requirements of Rule D.1301, a licensee shall establish a constraint on air emissions of radioactive material to the environment, excluding radon-222 and its decay products, so that the individual member of the public likely to receive the highest dose will not be expected to receive a total effective dose equivalent greater than 0.1 millisievert (10 millirem) per year from these emissions. If a licensee subject to this requirement exceeds this dose constraint, the licensee shall report the occurrence to the department as specified in Rule D.2203 and promptly take appropriate corrective action to ensure against recurrence.

Occupational Dose Limits

Rule D.1201 - Occupational Dose Limits for Adults.

a. A licensee or registrant shall control the occupational dose to individual adults, except for planned special exposures as specified in Rule D.1206, to the following dose limits:

   i. An annual limit, which is the more limiting of:

      (1) The total effective dose equivalent of 0.05 Sievert (5 rem); or

      (2) The sum of the deep dose equivalent and the committed dose equivalent to any individual organ or tissue other than the lens of the eye of 0.5 Sievert (50 rem).

   ii. The annual limits to the lens of the eye, to the skin of the whole body, and to the skin of the extremities which are:

      (1) A lens dose equivalent of 0.15 Sievert (15 rem); and

      (2) A shallow dose equivalent of 0.5 Sievert (50 rem) to the skin of the whole body or to the skin of any extremity.

b. A licensee or registrant shall subtract doses received in excess of the annual limits, including doses received during accidents, emergencies, and planned special exposures, from the limits for planned special exposures that the individual may receive during the current year and during the individual's lifetime. The dose limits for planned special exposures are provided in Rules D.1206e.i. and ii.

c. When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent shall be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the department.

d. The assigned deep dose equivalent shall be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent shall be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure.

    i. If the individual monitoring device was not in the region of highest potential exposure or the results of individual monitoring are unavailable, the deep dose equivalent, lens dose equivalent, and shallow dose equivalent may be assessed from surveys or other radiation measurements to demonstrate compliance with the occupational dose limits.

    ii. When a protective apron is worn while working with medical fluoroscopic equipment and monitoring is conducted as specified in Rule D.1503, the effective dose equivalent for external radiation shall be determined as follows:

        (1) When only one individual monitoring device is used and it is located at the neck (collar) outside the protective apron, the reported deep dose equivalent shall be the effective dose equivalent for external radiation; or

        (2) When only one individual monitoring device is used and it is located at the neck outside the protective apron, and the reported dose exceeds 25 percent of the limit specified in Rule D.1201a., the reported deep dose equivalent value multiplied by 0.3 shall be the effective dose equivalent for external radiation; or

        (3) When two individual monitoring devices are worn, one under the protective apron at the waist and the other outside the protective apron at the neck, the effective dose equivalent for external radiation shall be assigned the value of the sum of the deep dose equivalent reported for the individual monitoring device located at the waist under the protective apron multiplied by 1.5 and the deep dose equivalent reported for the individual monitoring device located at the neck outside the protective apron multiplied by 0.04.

e. The derived air concentration (DAC) and annual limit on intake (ALI) values are presented in Table I of Appendix B and may be used to determine the individual's dose and to demonstrate compliance with the occupational dose limits. Requirements for record keeping of individual monitoring results are provided in Rule D.2106.

f. In addition to the annual dose limits, a licensee shall limit the soluble uranium intake by an individual to 10 milligrams in a week in consideration of chemical toxicity. Requirements for annual limits on intake for uranium are provided in Appendix B.

g. The licensee or registrant shall reduce the dose that an individual may be allowed to receive in the current year by the amount of occupational dose received while employed by any other person during the current year. Requirements for determining prior occupational exposure are provided in Rule D.2104.

Rule D.1202 - Requirements for Summation of External and Internal Doses.

a. If a licensee or registrant is required to monitor individual occupational dose by both Rules D.1502a. and b., the licensee or registrant shall demonstrate compliance with the dose limits in Rule D.1201 by summing external and internal doses. If a licensee or registrant is required to monitor individual occupational dose only by Rule D.1502a. or only by Rule D.1502b., then summation is not required to demonstrate compliance with the dose limits. The licensee or registrant may demonstrate compliance with the requirements for summation of external and internal doses by meeting the requirements of Rules D.1202b., c., and d. The dose equivalents for the lens of the eye, the skin, and the extremities are not included in the summation, but are subject to separate limits specified in Rule D.1201.

b. If the only intake of radionuclides is by inhalation, the total effective dose equivalent limit is not exceeded if the sum of the deep dose equivalent divided by the total effective dose equivalent limit, and one of the following, does not exceed unity:

   i. The sum of the fractions of the inhalation ALI for each radionuclide; or

   ii. The total number of derived air concentration-hours (DAC-hours) for all radionuclides divided by 2,000; or

   iii. The sum of the committed effective dose equivalents to all significantly irradiated organs or tissues (T) calculated from bioassay data using appropriate biological models and expressed as a fraction of the annual limit. An organ or tissue is considered significantly irradiated if, for that organ or tissue, the product of the weighting factors, w_T, and the committed dose equivalent, $H_{T,50}$, per unit intake is greater than 10 percent of the maximum weighted value of $H_{T,50}$, that is, $w_T H_{T,50}$, per unit intake for any organ or tissue.

c. If the occupationally exposed individual receives an intake of radionuclides by oral ingestion greater than 10 percent of the applicable oral ALI, the licensee shall account for this intake and include it in demonstrating compliance with the dose limits in Rule D.1201.

d. The licensee shall evaluate and, to the extent practical, account for intakes through wounds or skin absorption. The intake through intact skin is included in the calculation of DAC for hydrogen-3 and does not need to be further evaluated.

Rule D.1203 - Determination of External Dose from Airborne Radioactive Material.

a. When determining the external dose from airborne radioactive material, a licensee shall include the contribution to the deep dose equivalent, lens dose equivalent, and shallow dose equivalent from external exposure to the radioactive cloud.

b. If the airborne radioactive material includes radionuclides other than noble gases or the cloud of airborne radioactive material is not relatively uniform, airborne radioactivity measurements and DAC values shall not be used as the primary means to assess the deep-

dose equivalent. The determination of the deep dose equivalent to an individual shall be based on measurements using instruments or individual monitoring devices.

Rule D.1204 - Determination of Internal Exposure.

a. To assess the dose used to determine compliance with occupational dose equivalent limits, a licensee shall, when required by Rule D.1502, take suitable and timely measurements of:

   i. Concentrations of airborne radioactive materials in work areas; or

   ii. Quantities of radionuclides in the body; or

   iii. Quantities of radionuclides excreted from the body; or

   iv. Combinations of these measurements.

b. Unless respiratory protective equipment is used, as provided in Rule D.1703, or the assessment of intake is based on bioassays, the licensee shall assume that an individual inhales radioactive material at the airborne concentration where the individual is present.

c. If specific information is known about the physical and biochemical properties of the radionuclides taken into the body or the behavior of the material in an individual, a licensee may:

   i. Use that information to calculate the committed effective dose equivalent, and, if used, the licensee shall document that information in the individual's record; and

   ii. With prior approval of the department, adjust the DAC or ALI values to reflect the actual physical and chemical characteristics of airborne radioactive material, for example, aerosol size, distribution, or density; and

   iii. Separately assess the contribution of fractional intakes of Class D, W, or Y compounds of a given radionuclide to the committed effective dose equivalent. Requirements for annual limits on intake are provided in Appendix B.

d. If a licensee chooses to assess intakes of Class Y material using the measurements specified in subrules a.ii or a.iii. of this rule, the licensee may delay the recording and reporting of the assessments for up to 7 months, unless otherwise required by Rules D.2202 or D.2203. This delay allows the licensee to make additional measurements basic to the assessments.

e. If the identity and concentration of each radionuclide in a mixture are known, the fraction of the DAC applicable to the mixture for use in calculating DAC-hours shall be either:

   i. The sum of the ratios of the concentration to the appropriate DAC value, that is, D, W, or Y, from Appendix B for each radionuclide in the mixture; or

   ii. The ratio of the total concentration for all radionuclides in the mixture to the most restrictive DAC value for any radionuclide in the mixture.

f. If the identity of each radionuclide in a mixture is known, but the concentration of one or more of the radionuclides in the mixture is not known, the DAC for the mixture shall be the most restrictive DAC of any radionuclide in the mixture.

g. If a mixture of radionuclides in the air exists, a licensee may disregard certain radionuclides in the mixture if:

   i. The licensee uses the total activity of the mixture to demonstrate compliance with the dose limits specified in Rule D.1201 and complies with the monitoring requirements specified in Rule D.1502b.; and

   ii. The concentration of any radionuclide disregarded is less than 10 percent of its DAC; and

   iii. The sum of the percentages for all of the radionuclides disregarded in the mixture does not exceed 30 percent.

h. i. To calculate the committed effective dose equivalent, a licensee may assume that the inhalation of one ALI, or an exposure of 2,000 DAC-hours, results in a committed effective dose equivalent of 0.05 Sievert (5 rem). This assumption may only be made for radionuclides that have their ALIs or DACs based on the committed effective dose equivalent;

   ii. When the ALI and the associated DAC is determined by the nonstochastic organ dose limit of 0.5 Sievert (50 rem), the stochastic ALI, which is the intake of radionuclides that would result in a committed effective dose equivalent of 0.05 Sievert (5 rem), is listed in parentheses in Table I of Appendix B. In this case, the licensee may use the stochastic ALIs to determine the committed effective dose equivalent. When the licensee uses the stochastic ALIs, the licensee shall also demonstrate that the limit in Rule D.1201a.i.(2) is not exceeded.

Rule D.1206 - Planned Special Exposures.

A licensee or registrant may authorize an adult worker to receive doses in addition to and accounted for separately from the doses received under the limits specified in Rule D.1201 if the following conditions are satisfied:

a. The licensee or registrant authorizes a planned special exposure only in an exceptional situation when alternatives that might avoid the dose estimated to result from the planned special exposure are unavailable or impractical;

b. The licensee or registrant, and employer if the employer is not the licensee or registrant, authorizes the planned special exposure, in writing, before the exposure occurs;

c. Before a planned special exposure, the licensee or registrant ensures that each individual involved is:

   i. Informed, in writing, of the purpose of the planned operation;

   ii. Informed, in writing, of the estimated doses and associated potential risks and specific radiation levels or other conditions that might be involved in performing the task; and

iii. Instructed in the measures to keep the dose ALARA considering other risks that may be present;

d. Before allowing an individual to participate in a planned special exposure, the licensee or registrant determines prior doses pursuant to Rule D.2104b. for the lifetime of each individual involved;

e. Subject to Rule D.1201b., the licensee or registrant shall not authorize a planned special exposure that would cause an individual to receive a dose from all planned special exposures and all doses in excess of the limits to exceed:

i. The numerical values of any of the dose limits in Rule D.1201a. in any year; and

ii. Five times the annual dose limits in Rule D.1201a. during the individual's lifetime;

f. The licensee or registrant keeps records of a planned special exposure pursuant to Rule D.2105 and submits a written report to the department pursuant to Rule D.2204;

g. The licensee or registrant records the best estimate of the dose resulting from the planned special exposure in the individual's record and informs the individual, in writing, of the dose within 30 days after the date of the planned special exposure. The dose from planned special exposures shall not be considered in controlling the future occupational dose of the individual pursuant to Rule D.1201a. but shall be included in evaluations required by subrules d. and e. of this rule.

Rule D.1207 - Occupational Dose Limits for Minors.

The annual occupational dose limits for a minor are 10 percent of the annual occupational dose limits specified for an adult worker in Rule D.1201.

Rule D.1208 - Dose Equivalent to an Embryo/Fetus.

a. The licensee or registrant shall ensure that the dose equivalent to the embryo/fetus during the entire pregnancy, due to the occupational exposure of a declared pregnant woman, does not exceed 5 millisieverts (500 millirem). Records for doses to the embryo/fetus shall be kept according to Rule D.2106d.

b. The licensee or registrant shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman to satisfy the limit in Rule D.1208a.

c. The dose equivalent to the embryo/fetus is the sum of:

i. The deep dose equivalent to the declared pregnant woman; and

ii. The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

d. If the dose equivalent to the embryo/fetus has exceeded 4.5 millisieverts (450 millirem), when the woman declares the pregnancy to the licensee or registrant, the licensee or registrant shall be considered in compliance with subrule a. of this rule if the additional dose

equivalent to the embryo/fetus does not exceed 0.5 millisievert (50 millirem) during the remainder of the pregnancy.

Radiation Dose Limits for Individual Members of the Public

Rule D.1301 - Dose Limits for Individual Members of the Public.

a. A licensee or registrant shall conduct operations so that:

   i. The total effective dose equivalent to a member of the public from the licensed or registered operation does not exceed 1 millisievert (100 millirem) in a year, excluding dose contributions from:

      (1) Background radiation,

      (2) Medical administrations the individual has received,

      (3) Exposure to individuals administered radioactive material and released pursuant to Rule G.40,

      (4) Voluntary participation in medical research programs, and

      (5) The licensee's or registrant's disposal of radioactive material into sanitary sewerage in accordance with Rule D.2003;

   ii. The dose in any unrestricted area from external sources of radiation, excluding the dose contributions from individuals administered radioactive material and released pursuant to Rule G.40, does not exceed 0.02 millisievert (2 millirem) in any one hour;

b. If a licensee or registrant allows members of the public to have access to controlled areas, the dose limits for members of the public continue to apply to those individuals.

c Notwithstanding subrule (a)(i) of this rule, a licensee may allow a visitor to an individual who cannot be released, pursuant to Rule G.40, to receive an annual radiation dose greater than 1 millisievert (100 millirem) if:

   i The annual radiation dose received does not exceed 5 millisieverts (500 millirem); and

   ii The authorized user, as defined in Part G, has determined before the visits that the visits are appropriate.

d. A licensee may request an exemption under Rule D.2301 for a visitor functioning as a caregiver to an individual who cannot be released, pursuant to Rule G.40, to receive an annual radiation dose greater than 5 millisieverts (500 millirem).

e. For individuals other than those covered in subrules c. and d. of this rule, a licensee, registrant, or an applicant for a license or registration may request authorization from the department to operate up to an annual dose limit for an individual member of the public of 5 millisieverts (500 millirem). The request shall include the following information:

i. Demonstration of the need for and the expected duration of operations in excess of the limit in subrule a of this rule; and

ii. A description of the licensee's or registrant's program to assess and control dose within the 5 millisieverts (500 millirem) annual limit; and

iii. The procedures to be followed to keep the dose as low as reasonably achievable.

f. The department may impose additional restrictions on radiation levels in unrestricted areas and on the total quantity of radionuclides that a licensee or registrant may release in effluents in order to restrict the collective dose.

Rule D.1302 - Compliance with Dose Limits for Individual Members of the Public.

a. A licensee or registrant shall make or cause to be made, as appropriate, surveys of radiation levels in unrestricted and controlled areas and radioactive materials in effluents released to unrestricted and controlled areas to demonstrate compliance with the dose limits for individual members of the public in Rule D.1301.

b. A licensee or registrant shall show compliance with the annual dose limit in Rule D.1301 by:

i. Demonstrating by measurement or calculation that the total effective dose equivalent to the individual who is likely to receive the highest dose from the licensed or registered operation does not exceed the annual dose limit; or

ii. Demonstrating that:

(1) The annual average concentrations of radioactive material released in gaseous and liquid effluents at the boundary of the unrestricted area do not exceed the values specified in Table 2 of Appendix B to this part; and

(2) The dose from external sources of radiation would not exceed 0.02 millisievert (2 millirem) in an hour and 0.5 millisievert (50 millirem) in a year if an individual were continuously present in an unrestricted area.

c. Upon approval from the department, the licensee or registrant may adjust the effluent concentration values in Table 2 of Appendix B to this part, for members of the public, to take into account the actual physical and chemical characteristics of the effluents, such as aerosol size distribution, solubility, density, radioactive decay equilibrium, and chemical form.

Surveys and Monitoring

Rule D.1501 - General.

a. A licensee or registrant shall make, or cause to be made, surveys that:

i. May be necessary to demonstrate compliance with the rules in this part; and

ii. Are reasonable under the circumstances to evaluate:
(1) The magnitude and extent of radiation levels; and

(2) Concentrations or quantities of radioactive material; and
(3) The potential radiological hazards.

b. A licensee or registrant shall ensure that instruments and equipment used for quantitative radiation measurements, for example, dose rate and effluent monitoring, are calibrated annually for the radiation measured, except as otherwise specified in another part of these rules or in a license or registration condition.

c. This subrule applies to personnel dosimeters, including dosimeters used to measure the dose to any extremity, that require processing to determine the radiation dose and that a licensee or registrant uses to comply with Rule D.1201, with other applicable provisions of these rules, or with conditions specified in a license or registration. This subrule does not apply to direct and indirect reading pocket dosimeters and electronic personal dosimeters. Personnel dosimeters shall be processed and evaluated by a dosimetry processor that:

i. Holds a current personnel dosimetry accreditation from the national voluntary laboratory accreditation program of the national institute of standards and technology; and

ii. Is approved in this accreditation process for the type of radiation or radiations included in the national voluntary laboratory accreditation program that most closely approximates the type of radiation or radiations for which the individual wearing the dosimeter is monitored.

Rule D.1502 - Conditions Requiring Individual Monitoring of External and Internal Occupational Dose.

A licensee or registrant shall monitor occupational exposure from sources of radiation at levels sufficient to demonstrate compliance with the occupational dose limits of this part.

a. A licensee or registrant shall monitor occupational exposure to radiation from sources of radiation under the control of the licensee or registrant and shall supply and require the use of individual monitoring devices by:

i. Each adult likely to receive, in 1 year from sources of radiation external to the body, a dose greater than 10 % of the limits specified in Rule D.1201a.; and

ii. Each minor likely to receive, in 1 year from sources of radiation external to the body, a deep dose equivalent greater than 1 millisievert (100 millirem), a lens dose equivalent greater than 1.5 millisieverts (150 millirem), or a shallow dose equivalent to the skin or to the extremities greater than 5 millisieverts (500 millirem); and

iii. Each declared pregnant woman likely to receive during the entire pregnancy, from sources of radiation external to the body, a deep dose equivalent greater than 1 millisievert (100 millirem); and

iv. Each individual who enters a high or very high radiation area;

v. Each individual for whom personnel monitoring is specifically required under other parts of these rules pertaining to specific uses of sources of radiation.

b. As specified in Rule D.1204, a licensee shall monitor the occupational intake of radioactive material by and assess the committed effective dose equivalent to:

   i. Adults likely to receive, in 1 year, an intake greater than 10 % of the applicable annual limit on intake in Table I, Columns 1 and 2, of Appendix B.

   ii. Minors likely to receive, in 1 year, a committed effective dose equivalent greater than 1 millisievert (100 millirem).

   iii. Declared pregnant women likely to receive, during the entire pregnancy, a committed effective dose equivalent greater than 1 millisievert (100 millirem).

Rule D.1503 - Location of Individual Monitoring Devices.

If Rule D.1502a or other Parts of these rules require occupational dose monitoring for an individual, the licensee or registrant shall ensure that the individual wears an individual monitoring device(s) as follows:

a. An individual monitoring device used for monitoring the dose to the whole body shall be worn at the unshielded location of the whole body likely to receive the highest exposure. When a protective apron is worn, the location of the individual monitoring device is typically at the neck ;

b. An individual monitoring device used to monitor the dose to an embryo/fetus of a declared pregnant woman, pursuant to Rule D.1208a., shall be worn at the waist under any protective apron being worn by the woman;

c. An individual monitoring device used for monitoring the lens dose equivalent, to demonstrate compliance with Rule D.1201a.ii.(1), shall be worn at the neck, outside any protective apron being worn by the monitored individual, or at an unshielded location closer to the eye;

d. An individual monitoring device used for monitoring the dose to the skin of the extremities, to demonstrate compliance with Rule D.1201a.ii.(2), shall be worn on the extremity likely to receive the highest exposure. Each individual monitoring device shall be oriented to measure the highest dose to the extremity being monitored.

Control of Exposure from External Sources in Restricted Areas

Rule D.1601 - Control of Access to High Radiation Areas.

a. A licensee or registrant shall ensure that each entrance or access point to a high radiation area has one or more of the following control features:

   i. A device that, upon entry into the area, causes the radiation level to be reduced below the level where an individual could receive a deep dose equivalent of 1 millisievert (100 millirem) in 1 hour at 30 centimeters from the source of radiation or from any surface that the radiation penetrates; or

ii. A device that energizes a conspicuous visible or audible alarm signal so that the individual entering the high radiation area and the supervisor of the activity are made aware of the entry; or

iii. Locked entryways, except when access to the area is required, with positive control over each individual entry.

b. In place of the controls required for a high radiation area by subrule a. of this rule, a licensee or registrant may substitute continuous direct or electronic surveillance that is capable of preventing unauthorized entry.

c. A licensee, registrant, or applicant for a license or registration may apply to the department for approval of alternative methods for controlling access to high radiation areas.

d. A licensee or registrant shall establish the controls required by subrules a. and c. of this rule in a way that does not prevent individuals from leaving a high radiation area.

e. A licensee or registrant is not required to control each entrance or access point to a room or other area that is a high radiation area solely because of the presence of radioactive materials prepared for transport and packaged and labeled according to U.S. department of transportation regulations if:

i. The packages do not remain in the area longer than 3 days; and

ii. The dose rate at 1 meter from the external surface of a package does not exceed 0.1 millisievert (10 millirem) per hour.

f. The licensee or registrant is not required to control entrance or access to rooms or other areas in hospitals solely because of the presence of patients containing radioactive material if:

i. Personnel are present who will take the necessary precautions to prevent the exposure of individuals to radiation or radioactive material greater than the limits established in this part; and

ii. The licensee or registrant operates within the as low as reasonably achievable provisions of the licensee's or registrant's radiation protection program.

g. The licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a high radiation area as described in Rule D.1601 if the licensee or registrant meets all the specific requirements for access and control specified in other applicable parts of these rules.

Rule D.1602 - Control of Access to Very High Radiation Areas.

a. Besides the requirements in Rule D.1601, a licensee or registrant shall institute additional measures to ensure that an individual cannot gain unauthorized or inadvertent access to areas in which radiation levels could be encountered at 5 gray (500 rad) or more in 1 hour at 1 meter from a source of radiation or any surface through which the radiation penetrates. This requirement does not apply to rooms or areas in which diagnostic X-ray systems are the only source of radiation, or to non-self-shielded irradiators.

b. A licensee or registrant is not required to control entrance or access to rooms or other areas containing sources of radiation capable of producing a very high radiation area as described in subrule a of this rule if the licensee or registrant meets all the specific requirements for access and control specified in other applicable parts of these rules.

Respiratory Protection and Controls to Restrict Internal Exposure in Restricted Areas

Rule D.1701 - Use of Process or Other Engineering Controls.

To the extent practical, the licensee shall use process or other engineering controls, such as containment, decontamination, or ventilation, to control the airborne concentrations of radioactive material .

Rule D.1702 - Use of Other Controls.

a. When it is not practical to apply process or other engineering controls to control the airborne concentrations of radioactive material to values below those that define an airborne radioactivity area, a licensee shall, consistent with keeping the total effective dose equivalent as low as reasonably achievable, increase monitoring and limit intakes of radioactive material by one or more of the following :

   i. Control access;

   ii. Limit exposure times;

   iii. Use respiratory protection equipment; or

   iv. Establish other controls.

b. If a licensee performs an ALARA analysis to determine whether respirators are necessary, the licensee may consider safety factors other than radiological factors. The licensee should also consider the impact of respirator use on workers' industrial health and safety.

Rule D.1703 - Use of Individual Respiratory Protection Equipment.

If the licensee assigns or allows the use of respiratory protection equipment to limit the intake of radioactive material:

a. The licensee shall use only respiratory protection equipment tested and certified by the national institute for occupational safety and health except as otherwise noted in this part;

b. A licensee may use respiratory protection equipment that the national institute for occupational safety and health has not tested or certified, or for which there is no schedule for testing or certification, if the licensee has submitted and the department has approved a request to authorize the use of the equipment, except as otherwise provided in this part. The request shall include documentation, based on testing by the licensee or on other reliable test information, that the material and performance characteristics of the equipment can provide the proposed degree of protection under the anticipated conditions of use;

c. A licensee shall implement and maintain a respiratory protection program that includes:

i. Air sampling sufficient to identify a potential hazard, permit proper equipment selection, and estimate doses;

ii. Surveys and bioassays, as necessary, to evaluate actual intakes;

iii. Testing of respirators for operability including user seal checks for face sealing devices and functional checks for other devices immediately before each use;

iv. Written procedures regarding:

(1) Monitoring, including air sampling and bioassays;

(2) Supervision and training of respirator users;

(3) Fit testing;

(4) Respirator selection;

(5) Breathing air quality;

(6) Inventory and control;

(7) Storage, issuance, maintenance, repair, testing, and quality assurance of respiratory protection equipment;

(8) Recordkeeping; and

(9) Limitations on periods of respirator use and relief from respirator use.

v. Determination by a physician that the individual user is medically fit to use the respiratory protection equipment :

(1) Before the initial fitting of a face sealing respirator;

(2) Before the first field use of a non-face sealing respirator, and

(3) Either every 12 months thereafter, or periodically at a frequency determined by a physician.

vi. Fit testing, with a fit factor greater than or equal to 10 times the assigned protection factor for negative pressure devices, and a fit factor greater than or equal to 500 for any positive pressure, continuous flow, and pressure-demand devices, before the first field use of tight fitting, face sealing respirators and annually thereafter . Fit testing shall be performed with the facepiece operating in the negative pressure mode.

d. A licensee shall advise each respirator user that the user may leave the area at any time for relief from respirator use if there is an equipment malfunction, physical or psychological distress, procedural or communication failure, significant deterioration of operating conditions, or any other condition that might require relief.

e. A licensee shall use respiratory protection equipment within the equipment manufacturer's expressed limitations for the type and mode of use. When selecting respiratory devices, the licensee shall provide for vision correction, adequate communication, low temperature work environments, and the concurrent use of other safety or radiological protection equipment. A licensee shall use the equipment so as not to interfere with the proper operation of the respirator.

f. Standby rescue persons are required whenever one-piece atmosphere-supplying suits, or any combination of supplied air respiratory protection devices and personnel protective equipment are used from which an unaided individual would have difficulty extricating himself or herself. The standby rescue personnel shall:

   i. Be equipped with respiratory protection devices or other apparatus appropriate for the potential hazards.

   ii. Observe or otherwise maintain continuous communication with the workers through visual, voice, signal line, telephone, radio, or other suitable means,

   iii. Be immediately available to help workers if the air supply fails or for any other reason that requires relief from distress.

   iv. Be immediately available in sufficient numbers to help all users of this type of equipment and to provide effective emergency rescue if needed.

g. Atmosphere-supplying respirators shall be supplied with respirable air of grade D quality or better as defined by ANSI/Compressed Gas Association G-7.1-2004, "Commodity Specification for Air," and included in the regulations of the occupational safety and health administration in 29 CFR 1910.134(i)(1)(ii)(A) through (E). Grade D quality air criteria include:

   i. Oxygen content between 19.5% and 23.5% by volume;

   ii. Condensed hydrocarbon content of 5 milligrams per cubic meter of air or less;

   iii. Carbon monoxide content of 10 parts per million or less;

   iv. Carbon dioxide content of 1,000 parts per million or less; and

   v. Lack of noticeable odor.

h. A licensee shall ensure that no objects, materials or substances, such as facial hair, or any conditions that interfere with the seal between the face and facepiece or the valve function, and that are under the control of the respirator wearer, are between the skin of the wearer’s face and the sealing surface of a tight-fitting respirator facepiece.

i. When estimating the dose to individuals from an intake of airborne radioactive material, the concentration of airborne radioactive material inhaled when respirators are worn is initially assumed to be the ambient concentration in air, without respiratory protection, divided by the assigned protection factor. If the dose is later found to be greater than the estimated dose, the corrected value shall be used. If the dose is later found to be less than the estimated dose, the corrected value may be used.

Rule D.1704 – Additional Restrictions on the Use of Respiratory Protection Equipment.

The department may impose restrictions in addition to the provisions of Rules D.1702 and D.1703, and Appendix A of this part, to:

a. Ensure that the respiratory protection program of the licensee is adequate to limit doses to individuals from intakes of airborne radioactive materials to keep the total effective dose equivalent as low as reasonably achievable; and

b. Limit the extent to which a licensee may use respiratory protection equipment instead of process or other engineering controls.

Rule D.1705 – Application for use of Higher Assigned Protection Factors.

A licensee shall obtain authorization from the department before assigning respiratory protection factors greater than those specified in Appendix A. The department may authorize a licensee to use higher assigned protection factors on receipt of an application that:

a. Describes the situation for which a need exists for higher protection factors; and

b. Demonstrates that the respiratory protection equipment provides these higher protection factors under the proposed conditions of use.

Security and Control of Sources of Radiation

Rule D.1801 - Security and Control of Sources of Radiation.

a. A licensee shall secure licensed radioactive material stored in a controlled or unrestricted area from unauthorized removal or access.

b. A licensee shall control and maintain constant surveillance of licensed radioactive material in a controlled or unrestricted area and not in storage.

c. A registrant shall use devices, administrative procedures, or both to prevent unauthorized use or removal of radiation machines.